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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/666,157 | 09/19/2003 | Kenneth W. Whitley | P-5655/5 | 7091 |
| 26253 | 7590 | 10/16/2007 | EXAMINER | |
| DAVID W. HIGGET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880 | | | BOWERS, NATHAN ANDREW | |
| ART UNIT | | PAPER NUMBER | | 1797 |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|-----------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/666,157 | WHITLEY, KENNETH W. |
| Examiner | Art Unit | |
| Nathan A. Bowers | 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 August 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,4,6-9,11 and 15-20 is/are pending in the application.
 - 4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 4, 6-9 and 11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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1) Claims 1, 4, 8, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mussi (EP 0614967) in view of Land (US 3630849), Weick (US 5908127) and Kayal (US 5695987).

With respect to claims 1, 4, 8 and 11, Mussi discloses a first roller bottle (Figure 1:24) for cell growth culturing comprising a cap (Figure 1:36). Page 3, line 33 to page 4, line 11 states that the first roller bottle is stacked adjacent to a second roller bottle. The second roller bottle comprises an elongate cylindrical wall having a closed bottom end and an opposing projecting neck portion (Figure 1:32) defining a liquid opening (Figure 1:34). The closed bottom end includes an inwardly directed recessed portion (Figure 1:42) for accommodating the cap of the first roller bottle. The recessed portion includes a side wall extending from the planar surface away from the neck portion end. Mussi, however, does not disclose that the side wall is configured so that a gap is defined between the side wall and an accommodated cap, or that an air space exists between the top of the cap of the first bottle and the recessed portion of the second bottle.

Land discloses a cell culture container comprising a closed top end and a closed bottom end. The bottom end includes an inwardly directed recessed portion for accommodating the top portion of an adjacent stacked similar container. The recessed portion further includes a planar surface and sidewalls. A plurality of ribs is provided on the container for defining a space between the top end of the similar container and the planar surface of the original container. This is disclosed in Figures 1 and 2, and in column 2, lines 29-42.

Mussi and Land are analogous art because they are from the same field of endeavor regarding cell culture devices.

At the time of the invention, it would have been obvious to utilize the ribs set forth by Land in the apparatus of Mussi in order to define an air space between the first and second bottles when they are in a stacked arrangement. In column 2, lines 39-42, Land indicates that ribs capable of facilitating air flow between adjacent stacked containers is beneficial because increased circulation promotes the maintenance of a uniform temperature during the culturing process.

The combination of Mussi and Land, however, still differs from Applicant's claimed invention because Land teaches that the ribs are provided on the cap of the cell culture container as opposed to on the closed bottom end.

Weick discloses a bottle comprising a cylindrical wall having a closed bottom end and an opposed projecting neck portion defining a liquid opening. Weick describes in column 6, lines 26-46 that the bottom end includes a recessed portion including a planar surface and side walls extending from the planar surface. A plurality of ribs (Figure 2:52) extend along the side walls for defining a space between the cap of a first bottle and the planar surface of a second bottle when the bottles are stacked.

Mussi and Weick are analogous art because they are from the same field of endeavor regarding bottle construction.

At the time of the invention, it would have been obvious to place ribs along the side walls of the recessed portion of the bottle disclosed by Mussi when altering the device of Mussi according to the teachings of Land. As evidenced by Weick, the construction of ribs along the base of a bottle to facilitate stacking is known in the art. The decision of whether to place ribs

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along the cap of a first bottle or along the side walls of a second bottle is simply a design choice, and does not affect the functionality of the resulting apparatus. The relocation of ribs from the cap portion to the recessed portion merely represents an obvious rearrangement of parts that does not result in a patentably distinct apparatus. See MPEP 2144.04.

The combination of Mussi, Land and Weick, however, still differs from Applicant's claimed invention because Land does not disclose that the cap of the first roller bottle has an open orifice formed therethrough.

Kayal discloses a cell culturing roller bottle (Figure 1:12) comprising a liquid opening that is covered by a screw cap. The cap includes a central orifice covered by a gas permeable membrane (Figure 3:56), and allows gases to enter into and out of the liquid opening. This is disclosed in column 1, lines 54-67.

Mussi and Kayal are analogous art because they are from the same field of endeavor regarding roller bottle cell culture devices.

At the time of the invention, it would have been obvious to alter the invention disclosed by Mussi in order to allow the space between the two coupled containers to permit the entry of gases into the liquid opening of the adjacent, bottom container. The addition of gases to a culturing vessel is often essential because many microorganisms require certain gases such as oxygen to grow. Kayal discloses in column 4, lines 6-17 that bottle caps comprising gas permeable membranes are an effective way to deliver critical gases to the culturing cells while preventing the passage of undesirable microorganisms and contaminants.

With respect to claim 9, Mussi, Land, Weick and Kayal disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. In addition, Mussi teaches that the bottle neck includes integral external screw threads for receiving an internally screw threaded cap. The cap has a top surface and an annular outer skirt extending from the top surface to a bottom stop ledge. This is apparent from the Figures.

2) Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mussi (EP 0614967) in view of Land (US 3630849), Weick (US 5908127) and Kayal (US 5695987) as applied to claim 1, and further in view of Pedmo (US 6585123).

Mussi, Land, Weick and Kayal disclose the roller bottle assembly set forth in claim 1 as set forth in the 35 U.S.C. 103 rejections above. In addition, Weick discloses that the plurality of ribs are equally spaced apart and radiate from a point proximal to the longitudinal axis of the container. This is clear from Figures 2-4 and 8.

Pedmo discloses a bottle comprising an inwardly directed recessed portion at the bottom of the bottle. Ribs (Figure 5:34) are provided, which radiate from a point proximal to the longitudinal axis of the container toward the sidewall of the recessed portion. A plurality of equally spaced apart ribs is provided. This is disclosed in column 2, lines 46-58.

Mussi and Pedmo are analogous art because they are from the same field of endeavor regarding the use of capped bottles to contain a fluid.

At the time of the invention, it would have been obvious to utilize a plurality of equally spaced apart, outwardly radiating ribs in the roller bottle assembly disclosed by Mussi. In column 1, lines 11-20, Pedmo discloses that ribs constructed in this manner are beneficial

because they improve the strength properties of the bottles, thus enabling the bottles to withstand damage when physically struck. Pedmo additionally states that a plurality of ribs that radiate from the center of the bottle help the bottles withstand deformation during heat applications. Since incubation is sometimes completed under high temperatures, the utilization of ribs of this nature would be beneficial in the roller bottle assembly disclosed by Mussi.

Response to Arguments

Applicant's arguments filed 02 August 2007 with respect to the combination of Mussi, Land, Weick and Kayal have been fully considered but they are not persuasive.

Applicant's principle arguments are

(a) Mussi, Land and Weick are not analogous art. The Examiner presents two completely different bases for claiming prior art is analogous.

In response to Applicant's arguments, please consider the following comments.

The Mussi, Land and Weick references disclose analogous art because each reference is directed to a stackable receptacle designed to retain a fluid. Since each reference discloses a different adaptation to facilitate stacking, one of ordinary skill in the art would know to evaluate the advantages presented in each reference when designing a stackable roller bottle.

(b) In formulating the rejection, the Examiner selectively chose aspects of four references, and it appears that the Examiner utilized impermissible hindsight reconstruction.

In response to Applicant's arguments, please consider the following comments.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Since Land teaches that the addition of ribs facilitates air flow between adjacent stacked containers, it would have been obvious to add ribs to the bottle of Mussi since increased air circulation promotes the maintenance of a uniform temperature during the culturing process.

As evidenced by Weick, the construction of ribs along the base of a bottle to facilitate stacking is known in the art. The decision of whether to place ribs along the cap of a first bottle or along the side walls of a second bottle is simply a design choice, and does not affect the functionality of the resulting apparatus. The relocation of ribs from the cap portion to the recessed portion merely represents an obvious rearrangement of parts that does not result in a patentably distinct apparatus.

Kayal discloses in column 4, lines 6-17 that bottle caps comprising gas permeable membranes are an effective way to deliver critical gases to the culturing cells while preventing the passage of undesirable microorganisms and contaminants.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

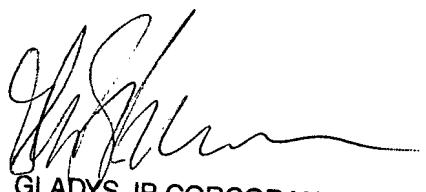
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NAB



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